

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2013-H-1372)

Complainant

v.

William Blair d/b/a Downsview General Store,

Respondent.

Docket No. C-14-159

Decision No. CR3332

Date: August 15, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a \$500 civil money penalty (CMP) action against Respondent for unlawfully selling cigarettes to minors, on three separate occasions, in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. During the hearing process, Respondent has failed to comply with three separate judicial directions to respond to a CTP request for documents. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

Respondent timely answered CTP's complaint proposing the CMP and requested a hearing. Administrative Law Judge Joseph Grow issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the March 31, 2014 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally the APHO stated that a party receiving such a request must provide the requested documents no later than 30 days after the request.

CTP served Respondent with its request for documents on March 7, 2014. On April 15, 2014, CTP filed a motion to compel discovery indicating that Respondent did not respond to its request within the time limit. *See* 21 C.F.R. § 17.23(a). CTP also moved to stay all deadlines citing Respondent's production of documents as necessary to complete its informal brief and supporting exhibits. On May 1, 2014, Judge Grow suspended all deadlines and provided Respondent another opportunity, within 10 days, to reply to CTP's motion to compel discovery or to otherwise file a motion for a protective order.

On May 6, 2014, however, Respondent prematurely filed his informal brief. CTP then moved to sanction Respondent for not complying with its document request and the ALJ's orders. CTP specifically requested that Judge Grow strike Respondent's submissions and enter an Initial Decision and Default Judgment against Respondent imposing the \$500 civil money penalty. Judge Grow held a teleconference to discuss the pending motion on June 23, 2014.

During the teleconference, Judge Grow reminded Respondent of his right to counsel. Judge Grow further informed Respondent, that if he chose to proceed without counsel, he would still be subject to the same rules as any other party, represented or not. *See June 30, 2014 Teleconference Summary and Order Scheduling Submission of Briefs and Evidence* at 2. Judge Grow deferred ruling on CTP's motion, granted Respondent yet another opportunity to comply and gave Respondent an additional 10 days from receipt of the latest order to either file a reply to CTP's request for documents or file a protective order. *Id.* at 2-3. The order also reminded the parties that they could face sanctions for not complying with any order. *Id.* at 4; 21 C.F.R. § 17.35(a) (1)-(3).

On July 16, 2014, the Director of the Civil Remedies transferred this case to me.

II. Pending Motions

On July 31, 2014, despite still not having filed any ordered response, Respondent emailed the staff attorney assigned to this case and moved to dismiss the case "for lack of a speedy trial." I deny Respondent's motion. Judge Grow explained the rules and deadlines for the progression of the hearing and decision process in his APHO, and Respondent has repeatedly ignored those deadlines and subsequent extensions. The fault for not reaching a hearing in this matter is attributable to Respondent's refusal to comply with legal authority and ALJ orders.

I therefore grant CTP's motion for sanctions by striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. §§ 17.35(c)(3), 17.11(a). The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find the failure to comply here egregious. *See* 21 C.F.R. § 17.35(b). Respondent did not comply with Judge Grow's orders on three occasions nor did he provide any adequate

justification for not doing so. The record contains no evidence that suggests the Respondent lacks the capacity to understand, conversely, it seems that Respondent understands but clearly does not intend to comply with procedures. Respondent has repeated the same pattern of non-compliance throughout these proceedings despite several opportunities to produce documents or file a protective order.

Judge Grow afforded Respondent every opportunity for due process. He scheduled a teleconference on June 23, 2014, during which he carefully explained Respondent's legal rights, obligations, and the procedures that would govern the case. He explained Respondent's options for responding to CTP's discovery request before the new deadline and duly extended the deadline to allow Respondent more time to respond. Finally, Judge Grow explained to Respondent the potential consequences of Respondent's failure to comply. Judge Grow once again provided this information to the parties in writing in his June 30, 2014 Teleconference Summary and Order Scheduling Submission of Briefs and Evidence.

Rather than making any effort to comply with the discovery request, by either producing documents or filing a protective order before the again extended deadline, Respondent simply submitted an e-mail on July 31, 2014, purporting to move for dismissal for lack of a speedy trial. Respondent stated that he had contacted FDA and tried to settle as the Judge suggested in his letter, without success. A July 31, 2014 e-mail from a representative of CTP's Office of Compliance and Enforcement indicates that two unsuccessful attempts were made to settle the case after the teleconference held by Judge Grow. Respondent's efforts to settle the case with CTP do not relieve him of the obligation, in the absence of a settlement, to comply with the regulations and Judge Grow's orders to respond to CTP's discovery request.

III. Default Decision

Striking Respondent's answer leaves the Complaint unanswered. Therefore, I am required to issue an initial decision by default if the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude that default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with Judge Grow's orders. 21 C.F.R. § 17.11. Specifically:

- At Respondent's business establishment, 8638 Downsville Pike, Williamsport, Maryland 21795, on September 20, 2011, at approximately 4:35 PM, an FDA-commissioned inspector observed Respondent's staff sell a package of Newport Box cigarettes to a person younger than 18 years of age;

